UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,576	01/16/2004	Jian-Bing Fan	067234-0104	8734

7590 04/26/2007

David A. Gray
MCDERMOTT WILL & EMERY LLP
4370 LaJolla Village Drive Suite 700
San Diego, CA 92122

EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,576	FAN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14-22 and 25-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,14 and 25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 7 February 2007 in which claims 1, 14, 28 were amended and claims 12-13, 23-24, 35-36 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 7 August 2006 under 35 U.S.C. 112, second paragraph, under 35 U.S.C. 102(b/e) and under 35 U.S.C. 103(a) are withdrawn in view of the amendments. The previous rejections under obviousness-type double patenting are maintained as reiterated below. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1-11, 14-22, 25-34 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 14, 15, 17, 19, 21, 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Chenchik (WO 99/35289, published 15 July 1999).

Regarding Claim 14, Chenchik discloses an array composition comprising a substrate having discrete sites (e.g. lane), each site comprising a plurality of different target analytes comprising sequences from different individuals (page 8, lines 14-26) wherein the targets are covalently attached (page 5, lines 29-32).

Regarding Claim 15, Chenchik discloses the array wherein the targets are covalently attached to the substrate (page 5, lines 29-32).

Regarding Claim 17, Chenchik discloses the array wherein the targets are nucleic acids (page 4, lines 10-20).

Regarding Claim 19, Chenchik discloses the array wherein the targets are proteins (page 4, lines 10-20).

Regarding Claim 21, Chenchik discloses the array wherein the substrate is plastic (page 6, lines 20-26).

Regarding Claim 22, Chenchik discloses the array wherein the discrete sites are wells (e.g. depressions or multi-well format, page 6, lines 27-29/page 10, lines 10-12).

4. Claims 14-15, 17, 19, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al (U.S. Patent No. 6,087,102, filed 7 January 1998).

Regarding Claim 14, Chenchik discloses an array composition comprising a substrate having discrete sites (e.g. lane), each site comprising a plurality of different target analytes comprising sequences from different individuals (Column 5, lines 51-67) wherein the targets are covalently attached (page 5, lines 29-32).

Regarding Claim 15, Chenchik discloses the array wherein the targets are covalently attached to the substrate (Column 3, line 65-Column 4, line 14).

Regarding Claim 17, Chenchik discloses the array wherein the targets are nucleic acids (Column 3, lines 17-25).

Regarding Claim 19, Chenchik discloses the array wherein the targets are proteins (Column 3, lines 17-25).

Regarding Claim 21, Chenchik discloses the array wherein the substrate is plastic (Column 4,lines 47-52page 6, lines 20-26).

Regarding Claim 22, Chenchik discloses the array wherein the discrete sites are wells (e.g. depressions or multi-well format, Column 4, lines 53-57/Column 6, lines 20-22).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-2, 5, 7-8, 10-11, 28-29, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (WO 98/40726, published 17 September 1998) in view of Chenchik et al (U.S. Patent No. 6,087,102, filed 7 January 1998) or Pinkel et al (U.S. Patent No. 5,830,645, filed 9 December 1994).

Regarding Claim 1, Walt et al disclose an array composition comprising a substrate having discrete sites and a population of microspheres comprising a first and second subpopulation, the microspheres of the subpopulations comprising a plurality of different target analytes e.g. antibodies and antigens (see Fig. 3 and Example 1, pages 24-25) wherein the microspheres are distributed on the surface (page 7, lines 5-15 and Fig. 5 and7). Walt et al further teach target analytes from different target source (e.g. rabbit, goat, mouse, Example

2, page 27, lines 9-16) but do not teach covalent attachment of target sequences from first and second individuals as newly claimed.

However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the microspheres of Walt et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

Regarding Claim 2, Walt et al disclose the array wherein each microsphere further comprise an optical signature (page 10, lines 4-5).

Regarding Claim 5, Walt et al disclose the array wherein the analytes are nucleic acids i.e. probe and target hybridized to the target (page 16, line 28-page 17, line 10 and Table V).

Regarding Claim 7, Walt et al disclose the array wherein the target analytes are proteins (e.g. antibodies and antigens, Example 2, page 27, lines 8-33).

Regarding Claim 8, Walt et al disclose the array wherein the substrate is a fiber optic (Abstract).

Regarding Claim 10, Walt et al disclose the array wherein the discrete sites are wells (page 20, lines 27-33 and Fig. 5).

Regarding Claim 11, Walt et al disclose the array wherein the microspheres are randomly distributed (page 7, lines 10-15).

Regarding Claim 28, Walt et al disclose a composition comprising a population of microspheres comprising a first and second subpopulation, the microspheres of the subpopulations comprising a plurality of different target analytes e.g. antibodies and antigens (see Fig. 3 and Example 1, pages 24-25) wherein the microspheres are distributed on the surface (page 7, lines 5-15 and Fig. 5 and7). Walt et al further teach target analytes from different target source (e.g. rabbit, goat, mouse, Example 2, page 27, lines 9-16) but does not teach covalent attachment of target sequences from first and second individuals as newly claimed.

However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the microspheres of Walt et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

Regarding Claim 29, Walt et al disclose the composition wherein each microspheres further comprise an optical signature (page 10, lines 4-5).

Regarding Claim 32, Walt et al disclose the composition wherein the analytes are nucleic acids i.e. probe and target hybridized to the target (page 16, line 28-page 17, line 10 and Table V).

Regarding Claim 34, Walt et al disclose the array wherein the target analytes are proteins (e.g. antibodies and antigens, Example 2, page 27, lines 8-33).

Regarding Claim 35, Walt et al disclose the array wherein the analytes of the different subpopulations are from different target source (e.g. rabbit, goat, mouse, Example 2, page 27, lines 9-16).

Regarding Claim 36, Walt et al disclose the array wherein the different sources are different patients (e.g. rabbit, goat, mouse, Example 2, page 27, lines 9-16). It is noted that the claim does not define the patient as human. Hence, the analytes from the animals listed above are encompassed by the claimed patient.

7. Claims 1-2, 5-11, 14-22, 25-29, 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410, filed 11 Sept 1998) in view of Chenchik et al (U.S. Patent No. 6,087,102, filed 7 January 1998) or Pinkel et al (U.S. Patent No. 5,830,645, filed 9 December 1994).

Regarding Claim 1, Walt et al disclose an array composition comprising a substrate having discrete sites and a population of microspheres comprising a first and second subpopulation, the microspheres of the subpopulations comprising a plurality of different target analytes e.g. antibodies and antigens (Fig. 3 and Column 27, lines 30-60) wherein the microspheres are distributed on the surface (Column 4, lines 35-50). Walt et al further teach the analytes of the different subpopulations are from different target source (e.g. rabbit, goat, mouse, Column 27, lines 30-60) but does not teach covalent attachment of target sequences from first and second individuals as newly claimed.

However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as

to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the microspheres of Walt et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

Regarding Claim 2, Walt et al disclose the array wherein each microsphere further comprise an optical signature (Column 4, lines 48-50).

Regarding Claim 5, Walt et al disclose the array wherein the analytes are nucleic acids i.e. probe and target hybridized to the target (Column 11, lines 25-35).

Regarding Claim 6, Walt et al disclose the array wherein the nucleic acids are genomic DNA (Column 11, lines 25-35).

Regarding Claim 7, Walt et al disclose the array wherein the target analytes are proteins (e.g. antibodies and antigens, Column 27, lines 30-60).

Regarding Claim 8, Walt et al disclose the array wherein the substrate is a fiber optic (Column 5, lines 24-31).

Regarding Claim 9, Walt et al disclose the array wherein the substrate is plastic (Column 5, lines 37-40).

Regarding Claim 10, Walt et al disclose the array wherein the discrete sites are wells (Column 5, lines 61-67).

Regarding Claim 11, Walt et al disclose the array wherein the microspheres are randomly distributed (Column 4, lines 46-48).

Regarding Claim 14, Walt et al disclose a composition comprising a substrate having discrete sites (i.e. sub-bundles, Column 18, lines 59-65), wherein each discrete site has a plurality of different target analytes (e.g. 5000 different bioactive agents, Column 18, line 65-Column 19, line 2) the bioactive agents covalently attached to the microspheres within the discrete sites (Column 11, lines 63-65). Walt et al does not teach covalent attachment of sequences from different individuals.

However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the microspheres of Walt et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

Regarding Claim 15, Walt et al disclose the composition wherein the analytes are covalently attached to the substrate i.e. the analytes are covalently attached to the microspheres which are covalently attached to the substrate (Column 6, lines 48-50 and Column 11, lines 63-65).

Regarding Claim 16, Walt et al disclose the composition wherein a plurality of different analytes are covalently attached to microspheres and the microspheres are distributed in the discrete sites i.e. the analytes are covalently attached to the microspheres which randomly

distributed and covalently attached to the substrate (Column 4, lines 42-55; Column 6, lines 48-50; and Column 11, lines 63-65).

Regarding Claim 17, Walt et al disclose the array wherein the analytes are nucleic acids i.e. probe and target hybridized to the target (Column 11, lines 25-35).

Regarding Claim 18, Walt et al disclose the array wherein the nucleic acids are genomic DNA (Column 11, lines 25-35).

Regarding Claim 19, Walt et al disclose the array wherein the target analytes are proteins (e.g. antibodies and antigens, Column 27, lines 30-60).

Regarding Claim 20, Walt et al disclose the array wherein the substrate is a fiber optic (Column 5, lines 24-31).

Regarding Claim 21, Walt et al disclose the array wherein the substrate is plastic (Column 5, lines 37-40).

Regarding Claim 22, Walt et al disclose the array wherein the discrete sites are wells (Column 5, lines 61-67).

Regarding Claim 25, Walt et al disclose the composition wherein the discrete sites are at a density of about 100,000 to 10,000,000 per cm^2 (Column 5, lines 4-31).

Regarding Claim 26, Walt et al disclose the composition wherein the discrete sites are at a density of about 10,000,000 to 1,000,000,000 per cm^2 (Column 5, lines 5-31).

Regarding Claim 27, Walt et al disclose the composition wherein the discrete sites are at a density of about 10,000 to 100,000 per cm^2 (Column 5, lines 4-31).

Regarding Claim 28, Walt et al disclose a composition comprising a population of microspheres comprising a first and second subpopulation, the microspheres of the subpopulations comprising a plurality of different target analytes e.g. antibodies and antigens (Fig. 3 and Column 27, lines 30-60) wherein the microspheres are distributed on the surface (Column 4, lines 35-50). Walt et al further teach the analytes of the different subpopulations are from different target source (e.g. rabbit, goat, mouse, Column 27, lines 30-60) but does not

teach covalent attachment of target sequences from first and second individuals as newly claimed.

However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the microspheres of Walt et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

Regarding Claim 29, Walt et al disclose the array wherein each microsphere further comprise an optical signature (Column 4, lines 48-50).

Regarding Claim 32, Walt et al disclose the array wherein the analytes are nucleic acids i.e. probe and target hybridized to the target (Column 11, lines 25-35).

Regarding Claim 33, Walt et al disclose the array wherein the nucleic acids are genomic DNA (Column 11, lines 25-35).

Regarding Claim 34, Walt et al disclose the array wherein the target analytes are proteins (e.g. antibodies and antigens, Column 27, lines 30-60).

8. Claims 1-11, 14-22, 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al (U.S. Patent No. 6,355,431, filed 3 March 2000 and claiming priority to 20 May 1999) in view of Chenchik et al (U.S. Patent No. 6,087,102, filed 7 January 1998) or Pinkel et al (U.S. Patent No. 5,830,645, filed 9 December 1994).

Regarding Claim 1, Chee et al disclose an array composition comprising a substrate having discrete sites and a population of microspheres containing first and second subpopulations wherein each microsphere comprises a plurality of different target analytes (i.e. capture probe and modified primer) wherein the microspheres are distributed on the surface. (e.g. amplifier probes, Column 34, line 32-Column 36, line 14). Chee does not specifically teach covalently attached target sequences from different individuals.

However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the microspheres of Chee et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

Regarding Claim 2, Chee et al disclose the array composition wherein the microspheres further comprising an optical signature (Column 38, lines 54-56).

Regarding Claims 3-4, Chee et al disclose the array composition wherein the microspheres further comprising a nucleic acid identifier binding ligand (Column 44, lines 8-60).

Regarding Claims 5-6, Chee et al disclose the array wherein the target analytes are genomic DNA (Column 8, lines 62-65).

Regarding Claim 7, Chee et al disclose the array wherein the analytes are proteins (e.g. IBL-DBL pairs, Column 44, lines 27-60).

Regarding Claim 8, Chee et al disclose the array composition wherein the substrate is a fiber optic (Column 38, lines 40-42).

Regarding Claim 9, Chee et al disclose the array composition wherein the substrate is plastic (Column 38, lines 31-33).

Regarding Claim 10, Chee et al disclose the array composition wherein the discrete sites are wells (Column 38, lines 31-33).

Regarding Claim 11, Chee et al disclose the array composition wherein the microspheres are randomly distributed on the surface (Column 38, lines 52-55).

Regarding Claim 14, Chee et al disclose a composition comprising a substrate comprising discrete sites wherein each site comprising a plurality of different covalently attached target analytes (i.e. analytes are covalently attached to the microspheres, Column 43, lines 56-57).). Chee does not specifically teach covalently attached target sequences from different individuals.

However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines

1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the microspheres of Chee et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

Regarding Claim 15, Chee et al disclose the composition wherein the analytes are covalently attached to the substrate (i.e. analytes are covalently attached to the microspheres, Column 43, lines 56-57, which are covalently attached to the wells, Column 42, lines 29-31).

Regarding Claim 16, Chee et al disclose the composition wherein the analytes are covalently attached to the microspheres (Column 43, lines 56-57) and the microsphere are distributed in discrete sites (Column 38, lines 52-55).

Regarding Claims 17-18, Chee et al disclose the array wherein the target analytes are genomic DNA (Column 8, lines 62-65).

Regarding Claim 19, Chee et al disclose the array wherein the analytes are proteins (e.g. IBL-DBL pairs, Column 44, lines 27-60).

Regarding Claim 20, Chee et al disclose the array composition wherein the substrate is a fiber optic (Column 38, lines 40-42).

Regarding Claim 21, Chee et al disclose the array composition wherein the substrate is plastic (Column 38, lines 31-33).

Regarding Claim 22, Chee et al disclose the array composition wherein the discrete sites are wells (Column 38, lines 31-33).

Regarding Claim 25, Chee et al disclose the composition wherein the discrete sites are at a density of about 100,000 to 10,000,000 per cm^2 (Column 39, line 52-Column 40, line 27).

Regarding Claim 26, Chee et al disclose the composition wherein the discrete sites are at a density of about 10,000,000 to 1,000,000,000 per cm^2 (Column 39, line 52-Column 40, line 27).

Regarding Claim 27, Chee et al disclose the composition wherein the discrete sites are at a density of about 10,000 to 100,000 per cm^2 (Column 39, line 52-Column 40, line 27). Regarding Claim 28, Chee et al disclose an array composition comprising a substrate having discrete sites and a population of microspheres containing first and second subpopulations wherein each microsphere comprises a plurality of different target analytes (e.g. capture probe and modified primer) wherein the microspheres are distributed on the surface. (e.g. amplifier probes, Column 34, line 32-Column 36, line 14).). Chee does not specifically teach covalently attached target sequences from different individuals.

However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the microspheres of Chee et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

Regarding Claim 29, Chee et al disclose the array composition wherein the microspheres further comprising an optical signature (Column 38, lines 54-56).

Regarding Claims 30-31, Chee et al disclose the array composition wherein the microspheres further comprising a nucleic acid identifier binding ligand (Column 44, lines 8-60).

Regarding Claims 32-33, Chee et al disclose the array wherein the target analytes are genomic DNA (Column 8, lines 62-65).

Regarding Claim 34, Chee et al disclose the array wherein the analytes are proteins (e.g. IBL-DBL pairs, Column 44, lines 27-60).

9. Claims 3, 4, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410, filed 11 Sept 1998) in view of Chenchik et al (U.S. Patent No. 6,087,102, filed 7 January 1998) or Pinkel et al (U.S. Patent No. 5,830,645, filed 9 December 1994) as applied to Claims 1 and 28 above and further in view of Dower et al (U.S. Patent No. 5,770,358, issued 23 June 1998).

Regarding Claims 3, 4, 30, 31, Walt et al disclose an array composition comprising a substrate having discrete sites and a population of microspheres comprising a first and second subpopulation, the microspheres of the subpopulations comprising a plurality of different target analytes e.g. antibodies and antigens (Fig. 3 and Column 27, lines 30-60) wherein the microspheres are distributed on the surface (Column 4, lines 35-50).

Walt et al do not teach the array/composition further comprising a nucleic acid identifier binding ligand. However, nucleic acid identifier binding ligands (oligo-tags) were well known and routinely practiced in the art at the time the claimed invention was made as taught by Dower et al (Abstract). Dower et al teach the oligo-tags are used to encode a library of compounds on microspheres and provide a dramatic improvement in library compound production and identification (Column 8, lines 40-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the microspheres

of Walt et al by attaching the oligo-tags that encode the bioactive agent. One of ordinary skill in the art would have been motivated to do so for the expected benefit of facilitating production and screening of the bioactive agent as taught by Dower et al (Column 4, line 66-Column 5, line 6 and Column 8, lines 40-47).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-35 of U.S. Patent No. 6,355,431 in view of Chenchik et al (U.S. Patent No. 6,087,102, filed 7 January 1998) or Pinkel et al (U.S. Patent No. 5,830,645, filed 9 December 1994).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a composition of microsphere populations on a substrate. The claim sets merely differ in that the patent claims define the microspheres as having capture probes while the instant claims define the capture probes in the independent claims as analytes and in dependent claims as proteins or nucleic acids. However, the genus

of capture probes recited in the patent claims is a relatively small groups such that nucleic acids and proteins would have been obvious to one of ordinary skill. Therefore, the instantly claimed compositions would have been an obvious application of the patent composition.

The patent claims do not define the microspheres as having different target sequences covalently. However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the patent microspheres . One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

12. Claims 1-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,544,732 in view of Chenchik et al (U.S. Patent No. 6,087,102, filed 7 January 1998) or Pinkel et al (U.S. Patent No. 5,830,645, filed 9 December 1994).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a composition of microsphere populations on a substrate. The claim sets merely differ in that the patent claims define the microspheres

as nanocrystals. However, the instantly claimed microspheres are generic to the patent nanocrystal microspheres. Furthermore, the instant claims define the microspheres as having two different analytes. However, the '732 specification defines use of the patent composition during which the patent microspheres comprise two analytes (Column 3, lines 21-33). Therefore, the patent specification defines the patent composition as comprising the second analyte as instantly claimed. Therefore, the claim sets are not patentably distinct.

The patent claims do not define the microspheres as having different target sequences covalently. However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the patent microspheres . One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

13. Claims 1-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,429,027 in view of Chenchik et al (U.S. Patent No. 6,087,102, filed 7 January 1998) or Pinkel et al (U.S. Patent No. 5,830,645, filed 9 December 1994).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a composition of microsphere populations on a substrate. The claim sets merely differ in the arrangement of limitations within the claim sets and further that the instant claims define the microspheres as having two different analytes. However, the '027 specification defines use of the patent composition during which the patent microspheres comprise two analytes (Column 5, lines 49-55). Therefore, the patent specification defines the patent composition as comprising the second analyte as instantly claimed. Therefore, the claim sets are not patentably distinct.

The patent claims do not define the microspheres as having different target sequences covalently. However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the patent microspheres . One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

14. Claims 1-5, 28-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,620,584 in view of

Chenchik et al (U.S. Patent No. 6,087,102, filed 7 January 1998) or Pinkel et al (U.S. Patent No. 5,830,645, filed 9 December 1994).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a composition of microsphere populations on a substrate. The claim sets merely differ in the terminology used to define the molecules of the microspheres. For example, the instant claims define the microspheres as having two analytes e.g. nucleic acid and nucleic acid identifier while the patent microspheres are defined as having a primer and decoding sequence. However, the primer and decoding sequences are defined in the patent specification as nucleic acids (Fig. 6-7). Therefore, the patent specification defines the patent composition as comprising the second analyte as instantly claimed. Therefore, the claim sets are not patentably distinct.

The patent claims do not define the microspheres as having different target sequences covalently. However, covalently attached target sequences were well known and routinely practiced in the art at the time the claimed invention was made as taught by Chenchik and Pinkel. Chenchik teaches target analytes from different sources covalently attached to a surface so as to maintain their position on the support under hybridization and washing conditions (Column 3, line 65-Column 4, line 14). Pinkel also teach target analytes covalently attached to microspheres thereby providing a highly efficient hybridization environments (Column 9, lines 1-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to covalently attach target sequences from different individuals to the patent microspheres. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing highly efficient hybridization environment whereby the targets maintain their position under hybridization and washing conditions as taught by Pinkel and Chenchik.

Response to Comments

15. Applicant has not traversed the previous rejections under obviousness-type double patenting. The rejections are maintained in view of the amendments as detailed above and made final.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
April 18, 2007